REMARKS

Reconsideration of the application in view of the above amendments and following remarks is requested. Claims 1, 2 and 8 are currently pending. Claims 3 and 4 have been canceled. Applicants reserve the right to prosecute cancelled subject matter in later filed applications and in no way are disclaiming any subject matter. Applicants assert that no new matter is added by the present amendment.

ELECTIONS/RESTRICTIONS

The Examiner has acknowledged Applicants election of Group I (claims 1-4 and 8) in the December 12, 2005 Response. However, in the November 18, 2005 Restriction Requirement, Applicants note that while Group IV was rightfully directed to the subject matter of claims 12 and 13, it was characterized as being directed to claims 9-11. Thus, Applicants assert that Section 4 of the Disposition of Claims should state that "Claims 1-13 are pending in the application" and Section 4a should state that "Of the above claims, 5-7 and 9-13 are withdrawn from consideration." Applicants respectfully request correction.

CLAIM OBJECTIONS

Claim 3 has been rejected under 37 CFR 1.75 as a duplicate of claim 4. Accordingly, Applicants have cancelled claim 4.

THE §101/§112, FIRST PARAGRAPH REJECTIONS

Claims 1-4 and 8 are rejected under 35 U.S.C. §101 and §112, first paragraph, alleging that the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

Applicants traverse. The present invention is based on the discovery of a novel class II cytokine, which Applicants designated Zcyto10 (also known as IL-20). Specifically, Zcyto10 is described as a four-helix-bundle cytokines such as those found within the interferon/IL-10 class:

It is believed that Zcyto10 is of a member of the IL-10 subfamily of cytokines. Other members of this group include MDA-7, IL-19, and KFF.

Id at pg. 9, lines 4-5. Concurrent with the discovery of Zcyto10, Applicants identified ZcytoR7 (IL-20RA) as a novel cytokine receptor: "ZcytoR7, like all known class II receptors except for interferon-alpha/beta receptor alpha chain, has only a single class II CRM in its extracellular domain. ZcytoR7 appears to be a receptor for a helical cytokine of the interferon/IL-10 class." *See e.g.* US Patent No. 5,945,511. As stated in the present Application, it was subsequently confirmed that Zcyto10 bound to a receptor complex comprising ZcytoR7. *See e.g.*, Blumberg et *al.*, Cell, 104:9-19, (2001) (copy enclosed).

The Examiner has alleged that the present Application "does not disclose a specific and substantial biological role of this protein or its significance...There is no biological activity, phenotype, disease or condition, or aay other specific feature that is disclosed as being associated with the IL-20 polypeptide."

Applicants strongly disagree. Applicants were the first to discover IL-20's biological function and its role in skin disorders. As stated in the present Application, IL-20 has been recognized to be involved with skin disorders: "Zcyto10 polypeptides can also be used to treat a number of skin conditions..., for example eczema, psoriasis or dry skin conditions in general or as related skin attentions." *See e.g.,* Specification at pg. 31, line 35 through pg. 36, line 3; *see also,* Blumberg et *al.* To support this utility, Applicants describe the **phenotypic effect** that IL-20 transgenic mice present in Example 5. Specifically, these transgenic mice exhibit skin that was "tight and wrinkled" while the "skin of the zcyto10 expressing pups, *particularly those mice which had a* ***high expression level of Zcyto10*** *tended to be thicker than the non-expressing pups."* *Id* at pg. 39. Applicants strongly assert that the present Application has clearly demonstrated that IL-20 has a biological role or function in skin conditions such as psoriasis. Thus, polynucleotides encoding the IL-20 protein would have clear utility.

Applicants have also enclosed a number of additional references that also support the asserted and specific utility that is clearly stated in the present Application. Rich and Kupper, Current Biology, 11:R531-R534 (2001) (copy enclosed), citing Applicants transgenic data summarized above, state that "Biological studies of IL-20 revealed that it has an important role in promoting hyperproliferation of keratinocytes and thereby modulating inflammation in the skin." Another reference, Volk *et al.*, TRENDS in Immunology, 22(8):414-417 (2001) (copy enclosed), ***also citing Applicants transgenic data***, state that IL-20's "selective pro-inflammatory activities make [it] interesting new candidates for research and drug development." Rich, B. E., Expert Opin. Ther. Targets, 7(2):165-174 (2003) (copy enclosed) states that "IL-20 signaling appears to be a prominent component of cutaneous inflammation." Rich goes on to state that "The apparently specialized role of IL-20 signaling in cutaneous tissue may present an opportunity to create pharmaceutical interventions that selectively mitigate inflammatory processes in the skin while sparing inflammation in other tissues." *Id.* Thus, as clearly stated in the present Application, IL-20 polypeptides would be useful in generating therapeutics for treating such skin conditions.

Accordingly, Applicants assert that the polynucleotides of the present invention encode an IL-20 polypeptide that has a recognizable biological function which would be understood and appreciated by one skilled in the art upon reading the present Application. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §101 and §112, first paragraph is respectfully requested.

The Examiner has also stated that Applicants "asserted utility" for Zcyto10 "to promote wound healing" is not specific or substantial because the Specification does not disclose a specific and substantial biological role for this protein or its significance.

Applicants strongly disagree. Applicants respectfully remind the Examiner that they "need only provide one credible assertion of specific and substantial utility." *See e.g.* M.P.E.P. §2107(II). Applicants strongly assert that they have in fact provided a credible, specific and substantial utility: **Zcyto10 is useful in promoting wound healing**. As stated in the M.P.E.P. §2107.01(I)(A) a "specific utility" is one where an Applicant "discloses a specific biological

activity" and "reasonably correlates that activity to a disease condition". As stated above, Applicants have indeed disclosed a "specific and substantial" biological activity for Zcyto10: to promote wound healing. Moreover, in Example 4, Applicants specifically disclose that Zcyto10 expression is up-regulated in wounded skin. Accordingly, Applicants assert that they have in fact disclosed a "specific utility": Applicants disclosed that Zcyto10 is upregulated in wounded skin" (*i.e.* a "specific biological activity") and thus would be useful in the treatment of burns or to promote wound healing (*i.e.* "reasonably correlates that activity to a disease condition").

The Examiner has also stated that the asserted utility is not presented in a "ready-to-use, real-world application" and, as such, "is not substantial."

Again, Applicants disagree. Applicants have also described to one skilled in the art how to use Zcyto10 for the treatment of such a burn or a wound. *See e.g.* Specification at pg. 34, lines 11-27. Applicants assert that one skilled in the art would easily recognize that the Zcyto10 would be useful to promote wound healing and how to use the same to promote such wound healing.

Furthermore, Applicants assert that the M.PE.P. §2107.01(I)(B) specifically states that Office personnel must be careful not to interpret the phrase "immediate benefit to the public" or other similar phrases to mean that products based on the claimed invention must be "currently available" in order to satisfy the utility requirement, but rather "***any reasonable use that an Applicant has identified that can be viewed as providing a public benefit should be accepted as sufficient.***" Further, the Courts have repeatedly found that the *mere identification* of a pharmacological activity that is relevant to the asserted use provides such "an immediate benefit to the public" and thus satisfies the utility requirement. *See e.g.* M.P.E.P. §2107.01(III)(A); *see also Nelson v. Bowler,* 626 F.2d 853, 856, 206 USPQ 881, 883 (CCPA 1980), which states:

> **Knowledge of the pharmacological activity of any compound is obviously beneficial to the public.** It is inherently faster and easier to combat illnesses and alleviate symptoms when the medical profession is armed with an arsenal of chemicals having known pharmacological activities. Since it is crucial to provide researchers with an incentive to disclose pharmacological activities in as many compounds as possible,

> **we conclude that adequate proof of any such activity constitutes a showing of practical utility.**

In addition, the Courts have also found utility for therapeutic inventions that were at very early stages in development, based solely on the claimed biological activity of the compound:

> We perceive no insurmountable difficulty, under appropriate circumstances, **in finding that the first link in the screening chain, *in vitro* testing, may establish a practical utility for the compound in question.** Successful *in vitro* testing will marshal resources and direct the expenditure of effort to further *in vivo* testing of the most potent compounds, thereby providing an immediate benefit to the public, analogous to the benefit provided by the showing of an *in vivo* utility.

See e.g. In re Brana, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995). Accordingly, an Applicant is not required to demonstrate that a claimed invention is a fully effective drug for humans. *See e.g.* M.P.E.P. §2107.01(III).

Applicants assert that Zcyto10 has a specific and substantial asserted utility that would be easily recognizable, and understood and appreciated by one skilled in the art upon reading the present Application. The utilities of the claimed invention described above provide immediate benefit to the public. That is all that is required under 35 U.S.C. §101. Accordingly, Applicants respectfully request consideration and withdrawal of the present rejections under 35 U.S.C. §101 and §112.

THE §112, FIRST PARAGRAPH REJECTIONS FOR WRITTEN DESCRIPTION AND ENABLEMENT

The Examiner has rejected claims 1 and 2 under 35 USC § 112, first paragraph, as failing to comply with the written description and enablement requirements.

Applicants have amended claims 1 and 2 so that they no longer recite the percent identity language. Accordingly, Applicants believe that the present rejections under 35 U.S.C. §112, first paragraph are now moot.

THE §112, SECOND PARAGRAPH REJECTION

Claim 8 is rejected under 35 USC § 112, second paragraph, as failing to set forth the subject matter which applicants regard as their invention.

Applicants have amended claim 8 as suggested by the Examiner. Accordingly, Applicants believe that the present rejection is now moot.

CONCLUSION

On the basis of the above amendments and remarks, Applicants believe that each rejection has been addressed and overcome. Reconsideration of the application and its allowance are requested. If for any reason the Examiner feels that a telephone conference would expedite prosecution of the application, the Examiner is invited to telephone the undersigned at (206) 442-6558.

Respectfully Submitted,

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Enclosures:

Blumberg et *al.*, Cell, 104:9-19, (2001)
Rich and Kupper, Current Biology, 11:R531-R534 (2001)
Volk *et al.*, TRENDS in Immunology, 22(8):414-417 (2001)
Rich, B. E., Expert Opin. Ther. Targets, 7(2):165-174 (2003)

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